

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A sterile pharmaceutical composition of propofol ~~stored~~ in a container, ~~the composition comprising a container which includes a closure and a composition in the container, the composition in the container comprising propofol and less than about 10% by weight solvent for propofol, said container in which the composition is stored comprising a closure for said container,~~ wherein ~~said~~ the closure is inert to propofol.

2. (Currently Amended) The ~~composition of claim 1~~ sterile pharmaceutical composition in a container according to claim 1, wherein ~~said~~ the composition further ~~comprises comprising~~ an aqueous phase and protein.

3. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 2, wherein the protein is albumin.

4. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 3, wherein the albumin is present in an amount of from about 0.01% to about 5% by weight of the composition.

5. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 2, wherein the aqueous phase comprises water ~~of~~ for injection and a pH modifier.

6. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 2, wherein the composition comprises a tonicity agent.

7. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 3, wherein the pH modifier is sodium hydroxide.

8. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 6, wherein the tonicity agent is glycerin.

9. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 2, wherein the composition further comprises a surfactant.

10. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 1, wherein the composition further comprises a solvent for propofol.

11. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 10 wherein the solvent is a water-immiscible solvent.

12. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 11, wherein the water-immiscible solvent is selected from the group consisting of soybean, safflower, cottonseed, corn, coconut, sunflower, arachis, castor sesame, orange, limonene or olive oil, an ester of a medium or long-chain fatty acid, a chemically modified or manufactured palmitate, glycerol ester or polyoxyl, hydrogenated castor oil, a marine oil, fractionated oils, and mixtures thereof.

13. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 12, wherein the water-immiscible solvent is soybean oil.

14. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 10, wherein the solvent is selected from the group consisting of chloroform, methylene chloride, ethyl acetate, ethanol, tetrahydrofuran, dioxane, acetonitrile, acetone, dimethyl sulfoxide, dimethyl formamide, methyl pyrrolidinone, C1-C20 alcohols, C2-C20 esters, C3-C20 ketones, polyethylene glycols, aliphatic hydrocarbons, aromatic hydrocarbons, halogenated hydrocarbons and combinations thereof.

15. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 9, wherein the surfactant is selected from the group consisting of phosphatides, synthetic phospholipids, natural phospholipids, lecithins, ethoxylated ethers and esters, tocopherol polyethylene glycol stearate, polypropylene-polyethylene block co-polymers, polyvinyl pyrrolidone, and polyvinylalcohol and combinations thereof.

16. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 15, wherein the surfactant is selected from the group consisting of egg phosphatides, soya phosphatides, egg lecithins, soya lecithins, and compositions thereof.

17. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 16, wherein the surfactant is egg lecithin.

18. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 1, wherein the closure is coated with a material inert to propofol.

19. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 1, wherein the closure is comprised of a material that is itself inert to propofol.

20. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 19, wherein the material inert to propofol is selected from the group consisting of a fluoropolymer, silicone, and mixtures thereof.

21. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 19, wherein the material is selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, non-rubber, metal, and mixtures thereof.

22. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 19, wherein the material is selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, and mixtures thereof.

23. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 1, wherein the closure comprises bromobutyl rubber coated with a fluoropolymer.

24. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 1, wherein the closure comprises siliconized bromobutyl rubber.

25. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 1, wherein the closure comprises a non-rubber, or metal.

26. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 1, wherein the closure comprises chlorobutyl rubber coated with a fluoropolymer.

27. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 1, wherein the closure comprises siliconized chlorobutyl rubber.

28. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 1, wherein the composition comprises propofol in an amount of from about 0.1% to about 10% by weight of the composition, soybean oil in an amount of from about 0.5% to about 6% by weight of the composition, egg lecithin in an amount of from about 0.1% to about 5% by weight of the composition and human serum albumin in an amount of from about 0.1% to about 5% of the composition.

29. (Currently Amended) A sterile pharmaceutical composition of propofol ~~stored~~ in a container comprising a container which includes a closure and an oil-in-water emulsion for parenteral administration of propofol in the container,

~~said~~ the composition comprising an oil phase comprising propofol and less than about 10% by weight solvent for propofol and an aqueous phase comprising water for injection, and the composition further comprising a stabilizing layer for the oil phase, the stabilizing layer comprising a surfactant and a protein,

~~said container in which the composition is stored comprising a closure for the container,~~ wherein the closure is inert to propofol.

30. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 29, wherein the protein is selected from the group consisting of

albumins, globulins, immunoglobulins, lipoproteins, caseins, insulins, hemoglobins, lysozymes, alpha-2-macroglobulin, fibronectins, vitronectins, fibrinogens, lipases, peptides, enzymes, antibodies and combinations thereof.

31. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 29, wherein the surfactant is selected from the group consisting of phosphatides, synthetic phospholipids natural phospholipids, lecithins, ethoxylated ethers and esters, tocopherol polyethylene glycol stearate, polypropylene-polyethylene block copolymers, polyvinyl pyrrolidone, and polyvinylalcohol.

32. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 29, wherein the oil phase is propofol neat.

33. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 29, wherein the surfactant is lecithin and the protein is albumin.

34. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 29, wherein the oil phase includes a solvent, and wherein the solvent is selected from the group consisting of soybean, safflower, cottonseed, corn, coconut, sunflower, arachis, castor sesame, orange, limonene or olive oil, an ester of a medium or long-chain fatty acid, a chemically modified or manufactured palmitate, glycerol ester or polyoxyl, hydrogenated castor oil, a marine oil, fractionated oils, and mixtures thereof, chloroform, methylene chloride, ethyl acetate, ethanol, tetrahydrofuran, dioxane, acetonitrile, acetone, dimethyl sulfoxide, dimethyl formamide, methyl pyrrolidinone, C1-C20 alcohols, C2-C20 esters, C3-C20 ketones, polyethylene glycols, aliphatic hydrocarbons, aromatic hydrocarbons, halogenated hydrocarbons and combinations thereof.

35. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 34, wherein the solvent is soybean oil.

36. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 35, wherein the soybean oil is present in an amount of from about 0.5% to about 6% by weight of the composition.

37. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 33, wherein the egg lecithin is present in the composition in an amount of from about 0.1% to about 5% by weight of the composition and the albumin is present in the composition in an amount of from about 0.01% to about 5% by weight of the composition.

38. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 37, wherein the oil phase includes soybean oil.

39. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 38, wherein the soybean oil is present in an amount of from about 0.5% to about 6% by weight of the composition.

40. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 38, wherein the soybean oil is present in the composition in an amount of from about 0.5% to about 3% by weight of the composition.

41. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 31 comprising:

- a) about 1% to 2% by weight of propofol,
- b) 3-6% by weight of soybean oil,
- c) 0.2-1.0% by weight of egg lecithin,
- d) about 2.25% by weight of glycerin,
- e) sodium hydroxide,
- f) water to 100%, and
- g) pH between 5.0-8.5.

42. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 29, wherein the closure is treated with a material inert to propofol.

43. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 29, wherein the closure comprises a material that is itself inert to propofol.

44. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 42, wherein the material inert to propofol is selected from the group consisting of a fluoropolymer, silicone, and mixtures thereof.

45. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 43, wherein the material is selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, non-rubber, metal, and mixtures thereof.

46. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 46, wherein the material is selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, and mixtures thereof.

47. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 29, wherein the closure comprises bromobutyl rubber coated with a fluoropolymer.

48. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 29, wherein the closure comprises siliconized bromobutyl rubber.

49. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 29, wherein the closure comprises non-rubber, or metal.

50. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 29, wherein the closure comprises chlorobutyl rubber coated with a fluoropolymer.

51. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 29, wherein the closure comprises siliconized chlorobutyl rubber.

52. (Currently Amended) A sterile, injectable pharmaceutical composition ~~stored~~ in a container comprising a container which includes a closure and a composition in the container, the composition comprising:

a) microdroplets having a mean size of from about 20 nanometers to about 1000 nanometers, the microdroplets comprising a sphere of propofol surrounded by a stabilizing layer comprising a phospholipid and devoid of oils capable of supporting bacterial growth; and

b) a pharmaceutically acceptable injectable carrier,
~~the container in which the composition is stored comprising a closure for the container,~~ wherein the closure is inert to propofol.

53. (Currently Amended) The sterile, injectable pharmaceutical composition in a container according to claim ~~of claim~~ 52, wherein the composition further comprises albumin.

54. (Currently Amended) The sterile, injectable pharmaceutical composition in a container according to claim ~~of claim~~ 52, wherein the stabilizing layer includes albumin.

55. (Currently Amended) The sterile pharmaceutical composition sterile, injectable pharmaceutical composition in a container according to claim ~~of claim~~ 52, wherein the closure is coated with a material inert to propofol.

56. (Currently Amended) The sterile pharmaceutical composition sterile, injectable pharmaceutical composition in a container according to claim ~~of claim~~ 52, wherein the closure comprises a material that is itself inert to propofol.

57. (Currently Amended) The sterile pharmaceutical composition sterile, injectable pharmaceutical composition in a container according to claim ~~of claim~~ 55, wherein the material inert to propofol is selected from the group consisting of a fluoropolymer, silicone, and mixtures thereof.

58. (Currently Amended) The sterile pharmaceutical composition sterile, injectable pharmaceutical composition in a container according to claim ~~of claim~~ 56, wherein the material is selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, non-rubber, metal, and mixtures thereof.

59. (Currently Amended) The sterile pharmaceutical sterile, injectable pharmaceutical composition in a container according to claim ~~of claim~~ 55, wherein the material is selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, and mixtures thereof.

60. (Currently Amended) The sterile pharmaceutical composition sterile, injectable pharmaceutical composition in a container according to claim ~~of claim~~ 52, wherein the closure comprises bromobutyl rubber coated with a fluoropolymer.

61. (Currently Amended) The sterile pharmaceutical composition sterile, injectable pharmaceutical composition in a container according to claim ~~of claim~~ 52, wherein the closure comprises siliconized bromobutyl rubber.

62. (Currently Amended) The sterile pharmaceutical composition sterile, injectable pharmaceutical composition in a container according to claim ~~of claim~~ 52, wherein the closure comprises a non-rubber, or metal.

63. (Currently Amended) The sterile pharmaceutical composition sterile, injectable pharmaceutical composition in a container according to claim ~~of claim~~ 52, wherein the closure comprises chlorobutyl rubber coated with a fluoropolymer.

64. (Currently Amended) The ~~sterile pharmaceutical composition~~ sterile, injectable pharmaceutical composition in a container according to claim of claim 52, wherein the closure comprises siliconized chlorobutyl rubber.

Claims 65-67. (Canceled)

This listing of claims replaces all prior versions, and listings, of claims in the application.